UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff,

v.

Civil Action No. 04-1522-GMS

DAKOCYTOMATION CALIFORNIA INC.,

Defendant.

PLAINTIFF VENTANA MEDICAL SYSTEMS, INC.'S OPENING CLAIM CONSTRUCTION BRIEF

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I. NATURE AND STAGE OF THE PROCEEDING

This is an action for patent infringement. Plaintiff Ventana Medical Systems, Inc. ("Ventana") respectfully submits this Opening Claim Construction Brief, pursuant to ¶ 4 of the March 24, 2005 Scheduling Order. The parties' claim construction positions are set forth in the Joint Final Claim Chart (Oct. 3, 2005) (D.I. 38).

II. INTRODUCTION

Ventana is the assignee of U.S. Patent No. 6,827,901 ("the '901 patent") (Ex. A). entitled "Automated biological reaction apparatus." In this litigation, Ventana contends that defendant DakoCytomation California Inc. infringes at least claims 1-7, 20-22, 24-25, 30 and 45 of the '901 patent ("the asserted claims"). These asserted claims include both independent claims of the '901 patent—claims 1 and 45. As will be explained in detail below, Ventana and DakoCytomation dispute the construction of two phrases that appear in claims 1 and 45:

- "reagent agitation zone"; and
- "an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents."

The parties agree that the two phrases have the same meanings in claims 1 and 45.

III. THE TECHNOLOGY OF THE '901 PATENT

Ventana develops, manufactures, and markets proprietary instrument and reagent systems. These systems automate the procedures used for staining tissue samples on microscope slides, primarily for the purpose of diagnosing cancer and infectious diseases. The inventors of the '901 patent recognized the great need in pathology to automate the process of staining microscope slides with chemical reagents. See Ex. A at 1:35-59 and 2:33-35. In particular, they recognized the need for automated equipment that is capable of performing complex staining procedures rapidly, reliably, and reproducibly. See id. at 2:36-45. Accordingly, the patented

[&]quot;refers to the specified exhibit to the Declaration of Matthew R. Reed in Support of Plaintiff's Opening Claim Construction Brief, filed concurrently herewith.

invention in the asserted claims generally concerns an apparatus with two carousels (one that holds reagent containers and one that holds samples mounted on slides) and an air mixer for mixing reagents that are dispensed from the reagent containers onto the slides. *See id.* at 2:48-3:13, 25:14-18 and 30:16-20. A primary purpose of the air mixer is to increase the interaction of the reagent with the tissue samples mounted on the slides. *See id.* at 13:29-31.

IV. ARGUMENT

A. The Principles of Claim Construction

The claims of a patent define the scope of the invention. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). The interpretation of the patent claims is a question of law for the Court to decide. *See id.* at 391; *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

The "ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001) (holding that the claims did "not require elaborate interpretation")). However, because "the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The "first and most obvious source" to which a court looks "is the claim language itself." *Bayer Healthcare LLC v. Abbott Labs.*, No. 03-189-GMS, 2005 WL 2346890, at *4 (D. Del. Sept. 26, 2005) (J. Sleet) (citing *Phillips*, 415 F.3d at 1314). The second source is the specification, which is "the single best guide to the meaning of a disputed term." *Id.* The third source is the prosecution history. *See id.* Referring now to the first source of intrinsic evidence,

the "claims themselves provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314. "The claims define the scope of the right to exclude: the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim. The language of the claim frames and ultimately resolves all issues of claim interpretation." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002) (citations omitted). There is a heavy presumption that claim language has its ordinary meaning:

There is a heavy presumption that the terms used in claims mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.

Resonate Inc. v. Alteon WebSystems, Inc., 338 F.3d 1360, 1364 (Fed. Cir. 2003) (citations omitted). Thus, the most important indicator of the meaning of a claim term is its usage and context within the claim itself. See Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1387 (Fed. Cir. 2002) ("As usual, the most important indicator of the meaning of 'uniform' is its usage and context within the claim itself."); Phillips, 415 F.3d at 1314 ("To begin with, the context in which a term is used in the asserted claim can be highly instructive.").

In some instances, the specification can provide helpful information about the meaning of claim terms. However, a court must avoid the danger of reading limitations from the specification into the claim. See Phillips, 415 F.3d at 1323. "[C]laims are not to be interpreted by adding limitations appearing only in the specification." Electro Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994) (citations omitted). While the specification may indicate that certain embodiments are preferred, "particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments." KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000) (citation omitted). The written description in the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." Resonate Inc., 338 F.3d at 1364.

A third source of intrinsic evidence regarding the meaning of terms in patent claims is the prosecution history. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. There are some

limitations on the usefulness of the prosecution history, however, because it "often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

With respect to claim limitations written in means-plus-function form, 35 U.S.C. § 112, ¶ 6 allows a patentee to recite a function to be performed as a claim limitation rather than reciting structure or materials for performing that function. The construction of a means-plus-function limitation follows a two-step approach. First, a court must identify the claimed function. *See Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999). Once the function performed by the claimed means is identified, a court must then ascertain the corresponding structure in the written description that performs that function. *See id.* A disclosed structure corresponds to a claimed function "only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim." *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). In other words, the structure must be necessary to perform the claimed function. *See Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1352 (Fed. Cir. 2003).

The use of the term "means" in combination with a function invokes a presumption that the claim element is a means-plus-function element to which § 112, ¶ 6 applies. *See Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1356 (Fed. Cir. 1999). The typical form of a means-plus-function claim element is "means for . . ." performing a function. However, the function associated with the term "means" need not be explicit, as in "means for" Rather, the associated function may be indicated by functional language immediately preceding the term "means" in a claim element. *See id.* at 1356 (determining that "ink delivery means" is a means-plus-function limitation where the function is "ink delivery"). In such circumstances, if the claim does not recite any structure, a court may properly apply § 112, ¶ 6 to the interpretation of that element. *See id.*

B. The First Disputed Phrase: "Reagent Agitation Zone"

The first phrase that the parties dispute and that must be construed is "reagent agitation zone." This phrase appears in claim 1 of the '901 patent as follows:

a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface:

Ex. A at 25:7-13 (emphasis added).

In its proper context, the meaning of the phrase "reagent agitation zone" is plain on its face and does not require construction. To the extent any construction is necessary, the claim language makes clear that "reagent agitation zone" means an area "located on the slide's upper surface" where "adding and mixing [of] reagents" takes place. Id.

The phrase "reagent agitation zone" does not appear anywhere in the specification of the '901 patent. That phrase also was not defined during the prosecution of the '901 patent. Accordingly, this element should be given its ordinary meaning as set forth above.²

C. The Second Disputed Phrase: "An Air Mixer Comprising an Air Jet and an Air Supply Means Positioned Adjacent To a Said Reagent Agitation Zone for Mixing Reagents"

The second phrase that the parties dispute and that must be construed also appears in claim 1 of the '901 patent:

> an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents. said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

Ex. A at 25:14-18.

This second disputed phrase can best be understood by separately analyzing its three components: (i) "an air mixer" which includes (ii) "an air jet" and (iii) "an air supply means."

² Based on the Joint Final Claim Chart submitted to the Court, it appears that defendant may attempt to argue that during prosecution Ventana limited "reagent agitation zone" to something other than an area located on the slide's upper surface where adding and mixing of reagents takes place. Ventana does not understand the basis for such an argument. Accordingly, in its responsive brief to be filed on November 7, 2005, Ventana will respond to any such argument articulated by defendant.

The "Air Mixer" Is "Positioned Adjacent To a Said Reagent Agitation 1. Zone for Mixing Reagents"

The first component of the second disputed phrase is "an air mixer." A simple examination of the prosecution history regarding the second disputed phrase reveals that the "air mixer" is the structure that is "positioned adjacent to a said reagent agitation zone for mixing reagents."

More specifically, the '901 patent issued from Application 10/137.169 ("the '169 Application"). The '169 Application—filed as a continuation of a previous application—was accompanied by a preliminary amendment. See Ex. B. That preliminary amendment contains the original language of the second disputed phrase that eventually issued in claim 1 of the '901 patent. See id. at 2 (application claim 72). The original language stated:

air mixer positioned adjacent an air agitation zone for mixing reactants when in the air agitation zone

Ex. B at 2. This original language makes plain that the air mixer is the structure that is positioned adjacent to the agitation zone.

The Examiner issued an Office Action in which he rejected this original language under 35 U.S.C. § 112, ¶ 2. In particular, the Examiner rejected application claim 72:

[A]s being incomplete for omitting essential elements The omitted elements are: air mixer having a nozzle for directing air at an air agitation zone of the sample support for mixing reactants on the sample support.

Ex. C at 2.

In response to this rejection, Ventana amended the original language to include the additional components of the air mixer that the Examiner deemed necessary:

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents

Ex. D at 2 (underlines and strikethroughs in original, denoting material added and deleted by amendment). In its accompanying remarks, Ventana explained that it believed the rejection "has been overcome by amending claim 72 to recite the essential elements identified by the Examiner." Ex. D at 11. The Examiner agreed by thereafter dropping the § 112, ¶ 2 rejection.

See Ex. E (making no reference to § 112, \P 2).

Although Ventana's amendment added the "essential" components of the air mixer required by the Examiner, the amendment did not change the fact that the "air mixer" as a whole (which, after the amendment, included the essential "air jet" and "air supply means" components) is what is positioned adjacent to the agitation zone for mixing reagents.

Defendant appears to be arguing that it is the "air supply means" component of the "air mixer," rather than the "air mixer" as a whole, that is positioned adjacent to the reagent agitation zone. This argument is unsound because it ignores the prosecution history set forth above. The prosecution history plainly indicates that the "air supply means" is simply part of the "air mixer," and that the "air mixer" is what is positioned adjacent to the agitation zone.

2. The Proper Construction of "An Air Jet"

The second component of the second disputed phrase is "an air jet." Ventana submits that this component uses commonly understood words and, therefore, should be given its ordinary meaning. *See Phillips*, 415 F.3d at 1314 (when ordinary meaning is clear, claim construction "involves little more than the application of the widely accepted meaning of commonly understood words"). The ordinary meaning of "an air jet" is a stream of air. The claim language and the specification both support this proposed construction.

The language of claim 1 supports this interpretation by describing the "air mixer" as "directing a jet of air at the reagent agitation zone." Ex. A at 25:16-17. The claim language places no limitation on the shape of the air jet.

The specification also supports this plain-language construction. The patent teaches:

[T]he reagent solution is stirred on the surface of the biological sample by applying at least one *gas stream* to an area of the surface of the evaporation inhibiting liquid layer

Ex. A at 4:47-53 (emphasis added); *see also id.* at 12:61-64 (the reagent "is stirred on the surface of the biological sample by applying at least one *gas stream* 356 or 357 to an area of the surface of the evaporation inhibiting liquid layer 360") (emphasis added). The specification imposes no other limitations on this component and, most assuredly, does not impose any requirement

concerning the shape or contour of the stream of air. Similarly, nothing in the prosecution history suggests that "an air jet" should be given some special construction that differs from its ordinary meaning.

Defendant seeks to have the court define the term "air jet" to mean "a conical or cylindrical stream of air." Defendant's argument appears to be based on an effort to import this shape limitation from passages in the specification where the stream of air is described as a "gas jet or cone." *See* Ex. A at 23:22-23 (a "gas jet or cone 356A of, for example, air or the like") and 23:45-46 ("the center of the gas jet or cone 356A is approximately 2 mm above the surface of the slide"). Defendant's argument is unsound. The use of the word "or" in the specification highlights that the claimed "air jet" may take at least two forms. It may simply be a "gas jet" (i.e., a stream of gas without any shape restriction). Alternatively, it may take the shape of a cone of gas. There is nothing in the specification that requires the claimed "air jet" to be shaped conically or cylindrically, as defendant urges.

Moreover, defendant's position in this regard also violates at least two fundamental canons of claim construction. First, "claims are not to be interpreted by adding limitations appearing only in the specification." *Electro Med. Sys., S.A..,* 34 F.3d at 1054. Second, "particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments." *KCJ Corp.,* 223 F.3d at 1356 (citations omitted). *See also Johnson Worldwide Assocs., Inc. v. Zebco Corp.,* 175 F.3d 985, 989 (Fed. Cir. 1999) ("General descriptive terms will ordinarily be given their full meaning; modifiers will not be added to broad terms standing alone.").

3. The Proper Construction of "An Air Supply Means"

The third component of the second disputed phrase is "an air supply means." The parties agree that this limitation is written in means-plus-function form pursuant to 35 U.S.C. § 112, \P 6. The parties disagree, however, as to both the claimed function and the corresponding structure.

The function of the "air supply means" is to supply air. a.

The function claimed by the "air supply means" is to supply air. The Federal Circuit discussed a means-plus-function claim element that is strikingly similar to the one at issue here:

In this case, the claim element "ink delivery means" uses the term "means" in association with a function, namely "ink delivery." Although the phrase "means for" is not used, the phrase "ink delivery means" is equivalent to the phrase "means for ink delivery," because "ink delivery" is purely functional language. Furthermore, the claim does not recite disqualifying structure which would prevent application of § 112, ¶ 6. The magistrate therefore correctly applied § 112, ¶ 6 to the interpretation of this claim element.

Signtech USA, Ltd., 174 F.3d at 1356.

Signtech is indistinguishable from this case. Here, the component of the claim at issue, "air supply means," uses the term "means" in association with a function, namely "air supply." Just like the "ink delivery means" in Signtech is equivalent to reciting "means for ink delivery." the "air supply means" in the '901 patent is equivalent to reciting "means for air supply." This is so because "air supply" is purely functional language just as "ink delivery" was held to be purely functional language.

Furthermore, as in Signtech, the rest of the claim language of the second disputed phrase does not recite any "disqualifying structure" for the "air supply means." Consequently, "air supply means" should be interpreted under § 112, ¶ 6, and its claimed function is to supply air.

In an effort to create a noninfringement argument where none exists, defendant argues that the function of the "air supply means" is "mixing reagents." This argument is without merit. Although the words "for mixing reagents" appear in the second disputed phrase, these three words modify and explain what the "air mixer" does as a whole. They do not describe the function of the "air supply means" which, as explained above, is merely a component part of the "air mixer" that performs the function of supplying air. This conclusion is readily apparent from the prosecution history discussed above which reveals that the words "for mixing reactants [sic, reagents]" appeared in the original language of application claim 72 to modify the claimed "air mixer." The "air supply means" was then added by amendment as one of the essential components of the "air mixer."

In addition to the foregoing, the context of the words "for mixing reagents" as used in the claim also supports the conclusion that those words modify the "air mixer." The "air mixer" is used "for mixing reagents." The "air supply means" component of the "air mixer" supplies air so that the "air mixer" can mix the reagents. As the Federal Circuit has repeatedly held, "the context in which a term is used in the asserted claim can be highly instructive." *Phillips*, 415 F.3d at 1314; *see also Middleton, Inc.*, 311 F.3d at 1387 ("As usual, the most important indicator of the meaning of [the disputed term] is its usage and context within the claim itself.").

b. The structure corresponding to the "air supply means" is a nozzle.

The structure described in the specification that corresponds to the claimed function of the "air supply means" is a nozzle. For instance, the specification explicitly refers to two nozzles that supply air when it states: "The pressurized air is emitted by nozzles 351 and 355 (FIG. 17), stirring the reagent layer on the respective slides." Ex. A at 16:16-18; *see also id.* at 23:44-48 ("nozzle orifice 351A" supplying "the gas jet or cone"). The two nozzles described in the specification as elements 351 and 355 can be seen in Figure 17, reproduced here with arrows and labels added for convenience:

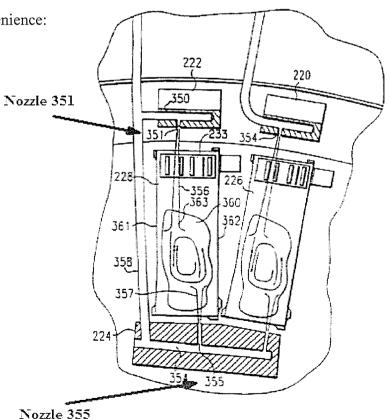


FIG. 17

In addition to the teachings of the specification, the prosecution history emphasizes that the "air supply means" is a nozzle. As previously noted, the Examiner rejected the original language of application claim 72:

[U]nder 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements The omitted elements are: air mixer having a nozzle for directing air at an air agitation zone of the sample support for mixing reactants on the sample support.

Ex. C at 2 (emphasis added). In response to this rejection, Ventana amended the claim as follows:

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents when in the air agitation zone Ex. D at 2 (underlines and strikethroughs in original, denoting material added and deleted by amendment). In its accompanying remarks, Ventana stated that it believed it had overcome the

Examiner's rejection by amending the claim "to recite the essential elements identified by the

Examiner." Id. at 11.

With respect to the nozzle that the Examiner deemed "essential," Ventana chose to claim that structure by using means-plus-function language, namely the "air supply means." Plainly, the Examiner agreed with Ventana's choice because the Examiner thereafter dropped the § 112. ¶ 2 rejection. See Ex. E (making no reference to § 112, ¶ 2). This is exactly the type of clear link between structure and function that the Federal Circuit has stated must be present. See B. Braun Med., Inc., 124 F.3d at 1424.

Despite the clear association both in the specification and the prosecution history between the "air supply means" and the disclosed nozzles, defendant demands more. Once again, in an effort to manufacture a noninfringement argument where none exists, defendant argues that the corresponding structure includes not only nozzles, but nozzles that form specific angles with the horizontal, as well as air supply channels and vortex mixer air jet blocks. This is entirely unsound for a number of reasons.

To begin with, defendant's argument is based on an erroneous understanding of the structure necessary to perform the claimed function. The only disclosed structure necessary for performing the claimed function is the nozzle.³ The Examiner stated that the essential element was a nozzle, not a nozzle plus an air supply channel plus a vortex mixer air jet block. See Ex. C at 2. Moreover, the specification states that "[t]he pressurized air is emitted by nozzles 351 and 355 (FIG. 17), stirring the reagent layer on the respective slides 234." Ex. A at 16:16-18. The law is plain that § 112, ¶ 6 does not permit "incorporation of structure from the written description beyond that necessary to perform the claimed function." Micro Chem., Inc., 194 F.3d at 1258. Defendant violates that prohibition here when it seeks to include air supply channels and vortex mixer air jet blocks.

Next, defendant's proposed structure improperly imports a requirement regarding the angular orientation of the nozzle that is neither recited in the claim, nor required to perform the claimed function of supplying air. Pertinent here is the decision in Genzyme Corp. v. Atrium Med. Corp., where the Court construed a means-plus-function element—a "dividing means" whose function was to divide one chamber from another. See 212 F. Supp. 2d 292, 324-25 (D. Del. 2002). There, the accused infringer observed that "horizontal partition 43" was the only partition disclosed in the specification for performing the dividing function. See id. Therefore, the accused infringer argued, the corresponding structure for the "dividing means" had to be limited to a horizontal partition. See id.

Not surprisingly, the Court rejected this argument, finding that the corresponding structure of the "dividing means" was a partition or a divider without any requirement that it be horizontal. See id. The Court explained that the invention did not require the dividing means to possess any particular orientation and that the orientation of the dividing means was irrelevant to the recited function of dividing the two chambers. See id. The Court noted that "limiting the dividing means to a structure having a certain specific orientation would improperly import limitations into the claim language." *Id.* (citing *Micro Chem., Inc.,* 194 F.3d at 1258).

³ The only disclosed structure necessary for performing the claimed function is the nozzle, regardless of whether the claimed function is determined to be "to supply air," as Ventana maintains, or "mixing reagents," as defendant erroneously contends.

Similarly in this case, the "air supply means" does not require the corresponding structure, the nozzle, to be at any particular angle because the claim itself does not recite any such requirement. Furthermore, the angle of the "air supply means" is irrelevant to the claimed function because, as explained above, the function simply is to supply air. Defendant's attempt to restrict the "air supply means" to a specific angular orientation would "improperly import limitations into the claim language." *Id*.

4. The Term "Adjacent" Does Not Require Construction

In addition to the phrases discussed above, defendant also asserts that the term "adjacent" must be construed. The term "adjacent" appears in the second of the two phrases disputed by the parties as follows:

an air mixer comprising
an air jet and
an air supply means
positioned *adjacent* to a said reagent agitation zone for mixing reagents,
said air mixer directing a jet of air at the reagent agitation zone thereby inducing
mixing in the reagent agitation zone.

Ex. A at 25:14-18 (emphasis added).

The meaning of the term "adjacent" is plain on its face and does not require construction. To the extent any construction is necessary, the plain and ordinary meaning of this term should apply and "adjacent" should be construed to mean near. This plain and ordinary meaning is consistent with the location of the air mixer as described in the specification. *See* Ex. A at 23:45-46 ("the center of the gas jet or cone 356A is approximately 2 mm above the surface of the slide"). Neither the plain and ordinary meaning nor the specification supports defendant's proposed construction that "adjacent" means next to, but not above or underneath. Moreover, the prosecution history does not alter the meaning of the term "adjacent."

V. CONCLUSION

For the foregoing reasons, Ventana respectfully requests the Court to construe the asserted claims of the '901 as proposed by Ventana.

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DATED: October 17, 2005

I, Richard H. Morse, hereby certify that on October 17, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing to the following counsel of record:

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I further certify that on October 17, 2005, I caused copies of the foregoing document to be served on the following non-registered participant in the manner indicated:

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